K071227

510(k) SUMMARY

JUL 11 2007

SUBMITTER INFORMATION

A. Company Name: Spectranetics Corporation, Inc.

B. Company Address: 96 Talamine Court
Colorado Springs, Colorado 80907

C. Company Phone: 719-633-8333 / 1-800-633-0960

D. Company Facsimile: 719-447-2040

E. Contact Person: Kelly W. Elliott, RN, MS
Vice President
Clinical Affairs & Regulatory Submissions

DEVICE IDENTIFICATION

A. Device Trade Name(s): CLiRpath® Turbo Excimer Laser catheters and TURBO elite™ Excimer Laser Catheters

Device Common Name(s): Peripheral Laser Catheters

B. Classification Name(s): Catheter, Peripheral, and Atherectomy

C. Device Class: Class II (per 21 CFR 870.4875)

D. Device Code(s): MCW

IDENTIFICATION OF PREDICATE DEVICES

Spectranetics TURBO elite™ excimer laser catheters are substantially equivalent to the same product line, TURBO elite™ excimer laser catheters (K060012). Spectranetics CLiRpath® Turbo excimer laser catheters are substantially equivalent to the same product line, CLiRpath® Turbo excimer laser catheter (K052296 and K052514)

DEVICE DESCRIPTION(S)

The CLiRpath® Turbo excimer laser catheters and the TURBO elite™ excimer laser catheters consist of a bundle of optical fibers, encased within medical grade tubing. The optical fibers conduct ultraviolet laser light (excimer laser light at 308 nm) from a source to the tip of the catheter. The catheter is inserted into a patient's vasculature along the length of a previously inserted guidewire, allowing the operator to deliver laser energy targeted to a lesion in the vasculature. The CLiRpath® Turbo and TURBO elite™ excimer laser catheters are provide in models designed for "over-the-wire" (OTW) or "rapid exchange" (RX) interventional techniques. Laser energy photoablates or debulks the lesion material re-establishing blood flow within the vessel and permits placement of other interventional devices if needed.

INTENDED USE(S)

The CLiRpath® Turbo and TURBO elite™ Excimer laser catheters: For use in the treatment of infrainguinal stenoses and occlusions.

COMPARISON(S) TO PREDICATE DEVICES

Spectranetics brand CLiRpath® Turbo and TURBO elite™ excimer laser catheters are equivalent in form, fit, and function to other Spectranetics excimer laser catheters intended for peripheral use. All Spectranetics peripheral excimer laser catheters are minimally invasive interventional devices used to treat arterial plaque in the arteries of a patient's leg in order to re-establish blood flow to the lower extremities.

BIOCOMPATIBILITY, STERILIZATION, PACKAGING, AND BENCH TESTING

CLINICAL DATA

Clinical data were collected in support of safety and efficacy for Spectranetics brand TURBO-Booster™ and CLiRpath® Turbo excimer laser catheters. Sixty-one (61) patients enrolled in the CELLO Study (CLiRpath Excimer Laser System to Enlarge Lumen Openings) approved as IDE #G060015. No major adverse events were recorded and the TURBO-Booster™ successfully facilitated placement of peripheral excimer laser catheters in 96.8% of the trial cases.

CONCLUSION

The above statements establishes substantial equivalence between the CLiRpath® Turbo and TURBO elite™ excimer laser catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

The Spectranetics Corporation
c/o Ms. Kelly W. Elliot, RN, MS
Vice President Clinical Affairs and Regulatory Submissions
96 Talamine Court
Colorado Springs, CO 80907-5186

SEP 18 2013

Re: K071227
Trade/Device Name: CLiRpath Turbo and Turbo Elite Excimer Laser Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: May 1, 2007
Received: May 3, 2007

Dear Ms. Elliot:

This letter corrects our substantially equivalent letter of July 11, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

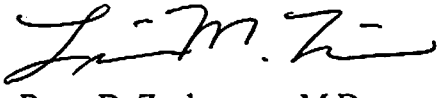
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7. Statement of Indication for Use

Device Name: CLiRpath® Turbo Excimer Laser Catheter

Indication for Use

For use in the treatment of infrainguinal stenoses and occlusions.

Device Name: TURBO elite™ Excimer Laser Catheter

Indication for Use

For use in the treatment of infrainguinal stenoses and occlusions.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071227